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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/602,597	06/22/00	DUHL	D 1568.002/200

EXAMINER	
WEBERT, S	
ART UNIT	PAPER NUMBER
1647	10

HM22/0223

CHIRON CORPORATION
INTELLECTUAL PROPERTY R338
PO BOX 8097
EMERYVILLE CA 94662-8097

DATE MAILED: 02/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/602,597	DUHL ET AL.	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to nucleic acids, vectors, host cells, and methods of producing polypeptides recombinantly, classified in class 435, subclass 69.1+.

II. Claims 10-16, drawn to polypeptides, classified in class 530, subclass 350+.

III. Claims 17-19, drawn to antibodies against a polypeptide, classified in class 536, subclass 23.5.

IV. Claim 20, drawn to a method of diagnosis using an antibody, classified in class 435, subclass 5+.

V. Claim 21, drawn to a method of diagnosis using DNA, classified in class 435, subclass 6.

VI. Claims 22 and 24, drawn to a method of treatment using protein, classified in class 424, subclass 130.1.

VII. Claims 23 and 25, drawn to a method of treatment using DNA, classified in class 514, subclass 44.

Furthermore, applicant is required to elect from one of the following groups.

a) Sequence ID 1 or 2

b) Sequence ID 3 or 4

c) Sequence ID 5 or 6

d) Sequence ID 7

e) Sequence ID 8 or 9

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventive Groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups I and II are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the polypeptides of Group II can be prepared by processes which are materially different from the recombinant DNA expression of Group I, such as by chemical synthesis, or by isolation and purification from natural sources. The DNA of Group I can be used other than to make the polypeptides of Group II, such as in gene therapy or as a probe in nucleic acid hybridization assays. Furthermore, the peptides of Invention II are related to the methods of Invention I as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05 (f)). In the instant case, the peptide may be isolated from its natural source or made by chemical synthesis.

The products and methods of Invention I are distinct from Invention III because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. Further, the

methods of Invention I can neither utilize the antibody of Invention III nor be used to make such a product. Furthermore, the methods of Invention I and Inventions IV-VII are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps, and goals.

The proteins of Invention II and the antibody of Invention III are distinct inventions because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The peptide of Invention II can be used for purposes other than to make an antibody of Group III, such as a probe, or used therapeutically or diagnostically (e.g. in screening).

Invention II is unrelated to Inventions IV, V, and VII. Inventions are unrelated if it can be shown that they are not capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. Inventions II and VI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptide of Invention II can be used to make the antibodies of Invention III.

Invention III is unrelated to Inventions V, VI, and VII. Inventions are unrelated if it can be shown that they are not capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. Inventions III and IV are

related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention III can be used for *in vitro* identification of protein, such as in flow cytometry, or for immunoprecipitation .

Furthermore, each set of sequences (a) – (e) represents a patentably distinct invention. Groups (a) through (e) are all independent and distinct, each from the other, because they have different putative functions, different structures and require completely different search terms, starting points and strategies.

Because these inventions are distinct for the reasons given above and the search required for each group is unique, and because each protein or nucleic acid of Groups (a) through (e) requires a completely separate search, as well as by their different classifications, divergent subject matter and different search requirements, restriction for examination purposes as indicated is proper.

In response to this requirement, applicants must elect from Groups I through VII, and must additionally elect from Groups (a) through (e). Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 8:30 AM to 5:00 PM (Eastern Time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

Feb 18, 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud